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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/877,150	06/17/97	ULLRICH A	225/298

022249
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HM12/0528

EXAMINER	
TENG,S	
ART UNIT	**PAPER NUMBER**
1646	13

DATE MAILED: 05/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/877,150	Applicant(s) Ullrich et al.
	Examiner Sally Teng	Group Art Unit 1646

☒ Responsive to communication(s) filed on *Jan 11, 1999* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-8 and 18-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-8 and 18-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Claims 1-8 and 18-20 are pending in the instant application.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The claims are directed to nucleic acids encoding BDP-1 while the title is directed to several polypeptides.

3. Applicant submitted a new Sequence Listing on March 30, 1999. However, the Sequence Listing is not accompanied with an amendment directing the entry of the Sequence Listing into the specification. Thus, the Sequence Listing submitted on March 30, 1999 has not been entered.

4. The specification and the claims do not comply with §1.821(d) of the Sequence Rules and Regulations. When the description or claims of a patent application discuss a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph (c) of the Sequence Rules and Regulation, reference must be made to the sequence by use of the assigned identifier, in the text of the description and claims of the patent application. Further, § 2422.02 of the MPEP states, "...when a sequence is presented in a drawing,...the sequence identifier (SEQ ID NO: X) must be used either in the drawing or in the Brief Description of Drawings." The brief description of each of the figures does not make reference to the respective sequence identifiers. Claims 3, 5, and 18 refer to sequences in figures, but do not recite the sequence identifiers for the figures.

5. Figure 3 discloses the amino acid and nucleic acid sequence for BDP1. Is SEQ ID NO: 36, the amino acid sequence shown in figure 3? However, it is pointed out that amino acid #9 of figure 3 is Arg while amino acid #9 of SEQ ID NO: 36 is Proline. It is suggested that applicant check all the sequences to make sure that those disclosed in the figures are the same as those disclosed in the Sequence Listing.

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims reads on products of nature because the term "nucleic acid probe" can be naturally occurring nucleic acid and a nucleic acid vector comprising a nucleic acid molecule also reads on naturally occurring vectors. It is suggested that the claims be amended to recite the term "isolated".

7. Claims 2, 7, 8, 18, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite. It is not clear as to how to enrich a nucleic acid molecule from a mammal.

In claims 7 and 20, it is not clear as to what is a recombinant tissue. Additionally it is not clear whether the recombinant host cell or tissue comprises the nucleic acid molecule endogenously or has been transformed or transfected with the nucleic acid encoding BDP1. A host cell could comprise the nucleic acid encoding BDP1 endogenously and be genetically manipulated to comprise a nucleic acid of another protein. On the other hand, if the claimed invention encompasses a tissue comprising the recited nucleic acid, then it seems that the claim reads on a product of nature, since human brain comprises BDP1.

In claim 8, it is not clear as to what is encompassed by the term "recombinant nucleic acid molecule". Does a recombinant nucleic acid have distinct properties? It is also not clear as to what is the claimed invention of claim 8. Is the claimed invention a vector comprising a nucleic acid encoding elements necessary for transcription of a desired nucleic acid sequence? It is also pointed out that transcription of the complement of the RNA sequence encoding a BDP1 yields a sequence that is identical to the coding strand, wherein T's are replaced by U's.

In claim 18, it is not clear as to what is encompassed by the term "naturally occurring BDP1 protein" (part (c)). The term "BDP1 polypeptide" is defined in the specification (page 12) as encompassing any polypeptide comprising 25 contiguous amino acids of figure 3. The specification defines the term as encompassing variants which are non-naturally occurring polypeptides. Part (d) is confusing because if the nucleotide sequence encodes a full length amino acid sequence as set forth in figure 3, then it cannot lack one or more of the domains. Additionally, it is not clear from figure 3 as to what is the "N-terminal domain", the "catalytic

domain", and the "C-terminal region". The amino acid sequence in figure 3 has not been marked up to indicate which residues are located in each of the structural domains.

8. Claim 3 is objected to under 37 CAR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 3 is an improper dependent claim because a BDP1 polypeptide is defined in the specification as having 25 or more contiguous amino acids of figure 3. A polypeptide having 12 contiguous amino acids of figure 3 is not a BDP1 polypeptide.

9. Claim 18(d) is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 18(d) is directed to a nucleic acid molecule encoding a polypeptide lacking one or more structural domains. However, the specification does not describe a nucleic acid molecule encoding a polypeptide lacking one or more structural domains. It is pointed out that if the catalytic domain is missing from the BPD1 polypeptide, then the polypeptide consists of the extracellular domain and the transmembrane domain linked to the C-terminal region. This

polypeptide is structurally and functionally distinct from the full length polypeptide. The specification only teaches one BPD1 polypeptide having SEQ ID NO: 36. The full length BDP1 polypeptide is not representative of polypeptides lacking one or more structural domains. Accordingly, claim 18(d) contains subject matter which was not described in the specification in such a way as to convey to one skilled in the relevant art that the inventor(s) at the time the application was filed, had possession of the claimed invention.

10. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding BDP1 having SEQ ID NO: 36, does not reasonably provide enablement for the broad genus of BDP1 polypeptides encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims as they stand are directed to nucleic acids encoding a broad genus of BDP1 polypeptides. Page 12 defines BDP1 as having 25 or more contiguous amino acids of Figure 3 or a functional derivative thereof. It is pointed out that a polypeptide having 25 contiguous amino acids would not have phosphatase activity because the entire catalytic domain is over 100 amino acids in length. The specification discloses one BDP1 polypeptide having SEQ ID NO: 36; however, the specification does not disclose other BDP1 polypeptides having the same functional activity as BDP1 comprising SEQ ID NO: 36 or BDP1 comprising 25 contiguous amino acids of

SEQ ID NO: 36. Neither the specification nor the prior art provides guidance as to the residues that are essential for BDP1 functional activity. It is not predictable as to what amino acids are essential for functional activity and what amino acids can be altered without affecting the functional activity of the protein. Without more guidance from the specification, it would require undue experimentation of the skilled artisan at the time the invention was made to make and or use the invention. Accordingly, since the specification does not enable the broad genus of BDP1 polypeptides, the specification does not enable the broad genus of nucleic acids encoding BDP1 polypeptides.

Claim 3 is directed to a nucleic acid molecule of claim 1, wherein the nucleic acid molecule encodes at least 12 contiguous amino acids of the full length amino acid sequence of figure 3. However, the nucleic acid molecule of claim 1 must also encode BDP1. The term "BDP1" is not defined in the specification as a polypeptide having 12 contiguous amino acids of the amino acid sequence set forth in figure 3. Thus, the specification does not enable claim 3.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-7 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al. (R54222)

Hillier discloses a nucleic acid that is identical to a portion of the nucleic acid encoding BDP1. The nucleic acid is isolated from a human source. It is a probe useful for the detection of BDP1 having at least 25 contiguous amino acids set forth in figure 3. It will hybridize under stringent condition to SEQ ID NO: 36. Hillier teaches Lafmid BA vector and a DH10B host containing the isolated nucleic acid. The only limitation recited in claims 1, 2, and 18 is that the nucleic acid encodes a naturally occurring BDP1 and hybridizes to the nucleic acid set forth in figure 3 of the present application. Claims 4 and 5 only include the limitation that the nucleic acid detects a nucleic acid encoding BDP1 having at least 25 contiguous amino acids of the sequence set forth in figure 3. Since the nucleic acid of Hillier is identical to a portion of the nucleic acid set forth in figure 3 of the present application, it must encode BDP1, hybridize to it under stringent conditions, and detect to BDP1 having at least 25 contiguous amino acids of figure 3. Thus, the claims are anticipated by Hillier.

12. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Ota et al.

Claim 3 as it stands is an improper dependent claim. However, claim 3 is interpreted as being directed to a nucleic acid encoding 12 contiguous amino acids of the sequence set forth in figure 3.

Ota discloses a nucleic acid encoding a tyrosine phosphatase that has 12 contiguous amino acids of the sequence set forth in figure 3 of the present application. Amino acids 227-238 of figure 3 of the present application is identical to amino acids 664-675 of figure 3 of Ota. Thus, the claim is anticipated by Ota.

13. Claims 1-8 and 18-20 rejected under 35 U.S.C. 102(a) as being anticipated by Cheng et al.

Although claim 8 is vague and indefinite, it is interpreted as directed to a RNA molecule.

Cheng teaches isolation of nucleic acid encoding a novel murine tyrosine phosphatase (page 1158 and fig. 1). The phosphatase of Cheng contains at least 25 contiguous amino acids of the sequence set forth in figure 3. Cheng also teaches vectors and host cells comprising the isolated nucleic acid (pages 1157 and 1158). Cheng discloses isolated RNA on Northern blots that encodes the phosphatase. Thus, the claims are anticipated by Cheng.

14. Claims 1-8 and 18-20 rejected under 35 U.S.C. 102(a) as being anticipated by Kim et al.

Kim discloses the nucleic acid encoding a human BDP1 tyrosine phosphatase having the amino acid sequence as set forth in figure 3 of the instant application (figure 1). Cheng also discloses vectors and host cells comprising the isolated nucleic acid (page 2278). In figure 3, Cheng discloses RNA molecule encoding BDP1. Thus, the claims are anticipated by Cheng.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally Teng, Ph.D., whose telephone number is (703) 308-4230. The examiner can normally be reached on Mon.-Fri. from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731.

Official papers filed by fax should be directed to (703) 305-3014. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 26, 1999

SALLY TENG
PRIMARY EXAMINER